

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Display Date	8-21-00
Publication Date	8-22-00
Certifier	SNReese

Food and Drug Administration

Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

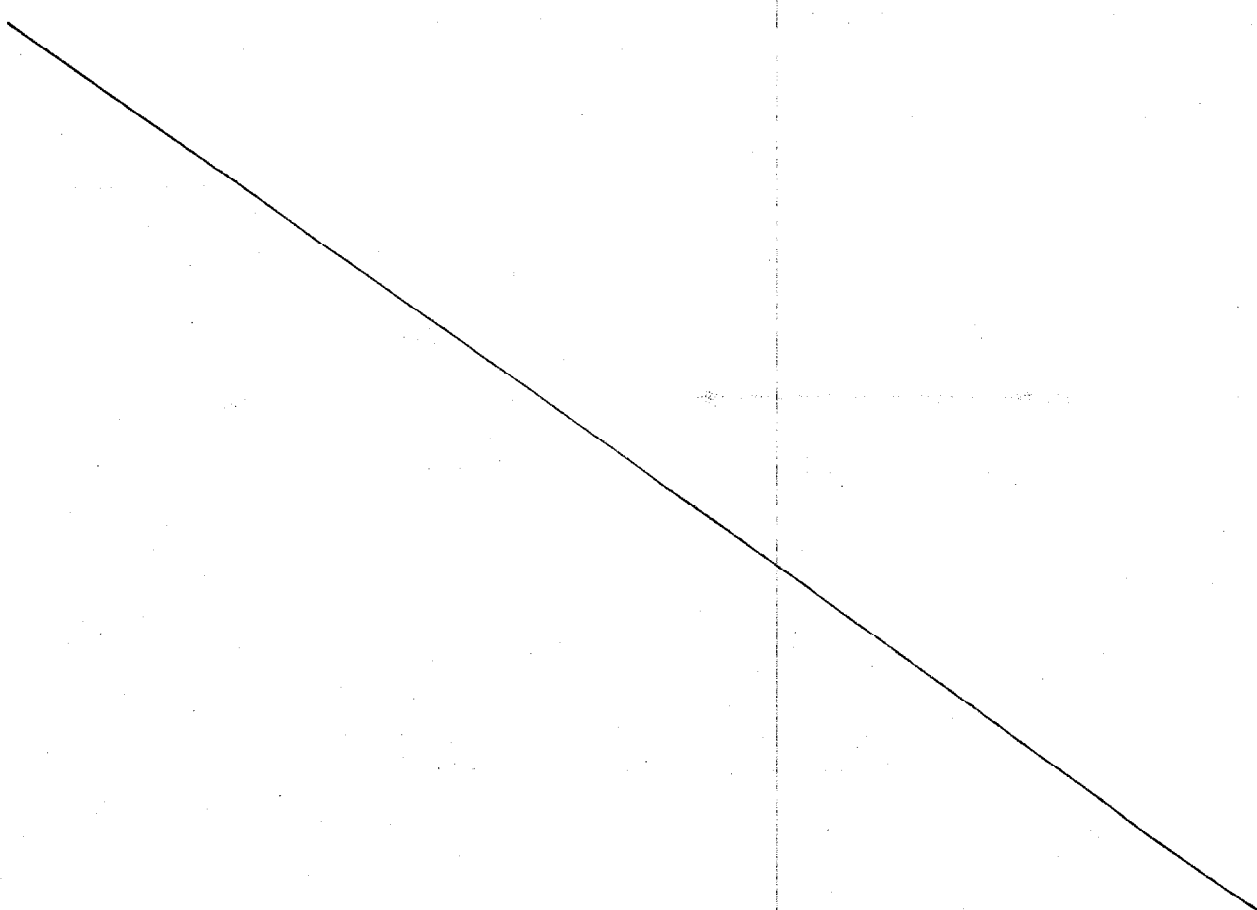
Date and Time: The meeting will be held on September 11, 2000, 8 a.m. to 5:30 p.m.

Location: Hyatt Regency, Baccarat/Haverford Rooms, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: at PETERSONJ@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 11, 2000, beginning at 8 a.m., the subcommittee will discuss ethical considerations in the conduct of placebo-controlled clinical trials in the pediatric population. Beginning at 3 p.m., the subcommittee will discuss the development of psychotropic drugs for use in young children.

Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the subcommittee. Written submissions may be made to the contact person by September 5, 2000. On September 11, 2000, oral presentations from the public will be scheduled between approximately 8:15 and 8:45 a.m. and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 5, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

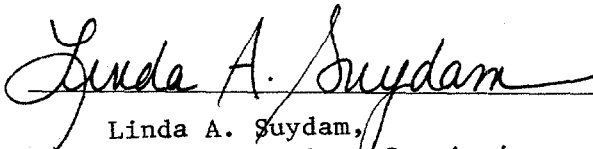


Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 8/10/00

August 10, 2000



Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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